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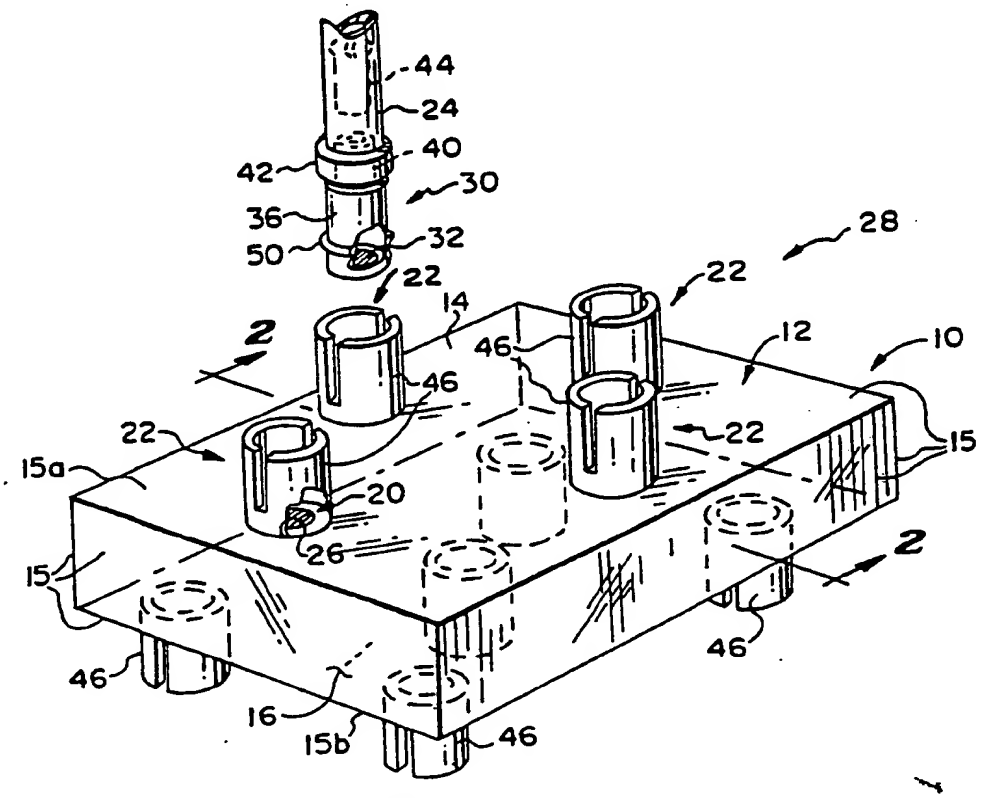
(54) Title: A STERILE FLUID TRANSFER SYSTEM AND AN ASSOCIATED MULTIPLE ACCESS FLUID TRANSFER DEVICE

(57) Abstract

A fluid transfer assembly includes a multiple access fluid transfer device (10) having a series of access ports (20), as well as two or more connector members (30) which are each attachable to a fluid conduit (24). Each access port (20) and each connector member (30) is normally sealed from communication with the atmosphere by a closure (26) (32) which can be removed only in conjunction with an active sterilization step. The connector member (30) is attachable to any of the access ports (20) with the respective closures (26 and 32) engaged in facing contact. During the active sterilization step, the closures are removed to form a sterile, hermetically sealed fluid path. Because multiple connections may be made in a sterile fashion using the assembly, the assembly is well suited for use in fluid systems associated with medical procedures, such as hyperalimentation therapy and peritoneal dialysis.



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A STERILE FLUID TRANSFER SYSTEM AND AN ASSOCIATED MULTIPLE ACCESS FLUID TRANSFER DEVICE

FIELD OF THE INVENTION:

This invention generally relates to systems and devices which serve to transfer fluids, and, in particular, systems and devices which transfer fluids in a sterile manner. This invention also generally relates to systems and devices which serve to intermix, or compound, fluids.

BACKGROUND AND OBJECTS OF THE INVENTION:

In some fluid networks, it is desirable to make multiple connections in as sterile a manner as is possible.

An example of such a fluid network is one associated with peritoneal dialysis. In this environment, dialysate is transferred directly into the peritoneal cavity of a patient. After about 3 to

4 hours, the dialysate is drained from the peritoneal cavity and replaced with fresh dialysate. This procedure requires a multiplicity of connections to be made on a daily basis to introduce and remove the dialysate. To minimize the risk of peritonitis, each connection must be made in as sterile a manner as possible. To this end, gloves, masks, gauze strips, and disinfectant solutions are typically employed. However, since these precautions often prove cumbersome and inconvenient, they are subject to neglect and human error.

Other examples of fluid networks involving multiple connections include those associated with chemical compounding and solution formulation. These include fluid networks which enable the compounding and infusion of medicines, pharmaceuticals, parenteral fluids, blood and blood components, and the like into the human body. A more specific example of this type of network is one involved in the compounding of hyperalimentation solutions.

Hyperalimentation therapy includes the intravenous feeding of a protein-carbohydrate mixture when the patient's protein and caloric requirements cannot be otherwise satisfied by oral feeding. The protein may consist of a free-amino acid or protein hydrolysate, and the carbohydrate can include dextrose. Vitamins and electrolytes can also be included in the protein-carbohydrate mixture. It is, of course, desirable that these mixtures be administered to the patient in a sterile condition.

These parenteral ingredients are particularly susceptible to the growth of deleterious organisms. Furthermore, for various reasons, hyperalimentation solutions cannot always be compounded by the manufacturer. Rather, they must be compounded in a sterile manner at the time of their use, for example, by a hospital pharmacist.

Typically, to insure sterility, these solutions are compounded under a device known as a laminar flow hood. This device operates by taking room air and passing it through a prefilter to remove airborne contaminants (such a dust and lint). The air is then compressed and channeled through bacterial retentive filter in the hood to remove all bacteria from the air.

While use of a laminar flow hood aids in preventing airborne contamination, it is relatively cumbersome and expensive. Furthermore, the hood does not eliminate all sources of contamination, such as contamination caused by handling.

It is thus one of the principal objects of this invention to provide a fluid transfer device and system which permits a multiplicity of connections to be made quickly and conveniently in a sterile fashion.

It is another one of the principal objects of this invention to provide a fluid transfer device and system which permits the formation, without reliance upon a laminar flow hood and the like, of multiple component solutions in a manner which does not breach the sterile integrity of any of the component ingredients or of the formed solution itself.

SUMMARY OF THE INVENTION:

To achieve these and other objects, the invention provides a fluid transfer device which enables a multiplicity of sterile connections to be made quickly and virtually in a foolproof manner.

The device which embodies the features of the invention includes a body having wall means which defines a hollow interior. Entry means is provided for defining at least two ports in the wall means. Means is provided for selectively attaching the end portion of a fluid conduit in communication with each of the ports. A flow of fluid into and through the hollow interior of the device can thus be established.

The device further includes closure means which extends across each of the ports and which normally seals the ports from communication with the atmosphere. Once sterilized, the sterile integrity of the interior of the device can thus be maintained.

In accordance with the invention, each of the closure means is removable to open the associated port. However, removal of each of the closure means requires an active sterilization step which serves to sterilize the fluid path formed through the port. Thus, an active sterilization step accompanies the establishment of fluid communication into and through the device.

In the preferred embodiment, the closure means is made of a material which melts in response to exposure to a source of radiant energy and at temperatures which result in the rapid destruction of any bacterial contamination on the surface of the material. In this embodiment, the wall means of the

body is preferably made of a material which is generally nonabsorbent of, and thus transparent to, the radiant energy used to melt the closure means. The wall means material thus passes the radiant energy without itself being heated to any great extent. This arrangement also promotes a fast and efficient transfer of radiant heat to melt the closure means.

Also, in the preferred embodiment, the wall means includes at least two diametrically spaced walls. In this arrangement, the entry means includes a plurality of ports in each of the diametrically spaced walls, each port being sealed by the meltable closure means. A multiplicity of connections can thus be accommodated upstream and downstream of the intended fluid flow path through the device.

Also, in this arrangement, the axis of each of the ports defined in one of the spaced walls is preferably laterally spaced from the axis of each of the ports defined in the other one of the spaced walls. By virtue of this arrangement, the energy used to melt the closure means can be easily focused through one wall upon a selected closure means defined in an opposite wall.

The invention also provides a fluid transfer assembly which includes the multiple access transfer device heretofore defined. In the assembly, the conduit attachment means of the device includes connector means which is attachable to the end of a fluid conduit and which is operative for engagement with each of the ports defined in the wall means.

Like each of the ports, the connector means includes closure means which normally seals each conduit end portion and which is removable only in conjunction with an active sterilization step.

In the preferred embodiment of the assembly, when the connector means is engaged with a selected one of the ports, the closure means of the port and the closure means of the connector means are held in facing contact. In this arrangement, the facing closure means are further operative for jointly melting to form a fluid path through the facing portions, but only in response to exposure to sterilizing temperatures. Thus an active sterilization step occurs simultaneously with the formation of the fluid path.

The invention also provides a sterile fluid transfer system which includes a multiple access fluid transfer assembly as heretofore defined. The system also includes at least one source of fluid and at least one fluid receiving receptable. In this arrangement, one connector means of the fluid transfer assembly communicates with the fluid source and the receiving receptacle. Use of this system enables the transfer of fluids from one or more of the sources into the fluid receiving receptacle or receptacles in a sterile manner.

Other features and advantages of the invention will be pointed out in, or will be apparent from, the specification and claims, as will obvious modifications of the embodiments shown in the drawings.

DESCRIPTION OF THE DRAWINGS:

Fig. 1 is a perspective view, with portions broken away, of a multiple access fluid transfer assembly which embodies the features of the invention;

Fig. 2 is a partial section view generally taken along line 2-2 in Fig. 1 and which shows the multiple access fluid transfer device and connector means which together comprise the assembly shown in Fig. 1;

Fig. 3 is an enlarged section view of the multiple access fluid transfer assembly shown in Fig. 2 with the connector means coupled to the transfer device and being exposed to a source of radiant energy to open a fluid path therethrough;

Fig. 4 is an enlarged section view of the assembly shown in Fig. 3 after the fluid path has been opened between the connector means and the transfer device;

Fig. 5 is a sterile fluid transfer system which includes the fluid transfer assembly which is shown in Fig. 1; and

Fig. 6 is a sterile fluid transfer system which includes another embodiment of a multiple access fluid transfer assembly which embodies the features of the invention.

Before explaining the embodiments of the invention in detail, it is to be understood that the invention is not limited in its application to the details of the construction and to the arrangement of components as set forth in the following description or as illustrated in the accompanying drawings. The invention is capable of other embodiments and of

being practiced or carried out in various ways. Furtheremore, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

DESCRIPTION OF THE PREFERRED EMBODIMENT:

A multiple access fluid transfer device 10 is shown in Fig. 1. The device includes a body 12 having wall means 14 which defines a hollow interior 16.

The device 10 also includes entry means which defines at least two access ports 20 in the wall means 14. The ports 20 open the hollow interior 16 of the device 10 to communication with the atmosphere.

The device 10 also includes means 22 which accommodates the attachment of the end portion of a conduit 24 in fluid communication with any of the ports 20. Fluid flow into and through the hollow interior 16 of the device 10 can thus be established.

The body 12 of the device 10 may be variously constructed. In the illustrated embodiment, the body 12 constitutes an injection molded plastic part.

Furthermore, while the particular shape of the device 10 may vary, in the illustrated embodiment, the device 10 takes the form of a generally rectangular box. In this configuration, the wall means 14 includes three pairs of diametrically spaced walls 15 (i.e., a total of six walls 15) which collectively define the hollow interior 16.

In the illustrated arrangement, the ports 20 are formed only in a selected pair of the diametrically spaced walls 15. In the illustrated embodiment, when the device 10 is positioned as shown in Fig. 1, these walls constitute the top, or upstream, wall (designated 15a in Fig. 1) and the bottom, or downstream, wall (designated 15b in Fig. 1) of the device 10. Such an arrangement facilitates the gravity flow of fluids into and through the device 10.

The number of ports 20 can vary according to the intended function of the device 10. In the illustrated embodiment, a plurality of ports 20 are associated with each of the selected pair of walls 15a and b.

The device 10 further includes closure means 26 which extends across each of the ports 20 to normally seal the ports 20. The hollow interior 16 of the device 10 is thus normally sealed by the closure means 26 from communication with the atmosphere.

Each of the closure means 26 is selectively removable to open a fluid path through the associated port 20.

The closure means 26 may be variously constructed and employ different means of operation. However, to meet the desired objectives of the invention, the closure means 26 must (1) normally close each port 20 from communication with the atmosphere, and (2) be removable only in conjunction with an active sterilization step which serves to sterilize the regions adjacent to the fluid path through each port 20 as the port 20 is opened.

It has been determined that the closure means associated with the connector described in Granzow et al U.S. Patents 4,157,723 and 4,265,280 meets the above criteria. For this reason, this embodiment of the closure means 26 is preferred, and the disclosures of these patents are incorporated herein by reference.

More particularly, in the illustrated and preferred embodiment, the closure means 26 is made of a meltable material which absorbs radiant, or electromagnetic, energy, such as radio waves, infrared waves, visible light, ultraviolet waves, x-rays, and the like.

Because radiant energy is used, no intervening medium is required to transfer the heat, as in conductive or convective heat transfer. A fast and efficient transfer of heat is thus provided.

Furthermore, the material of closure means 26 is purposely selected so that it melts only in response to temperatures sufficient to rapidly destroy any bacterial conntaminant on the surface of the material.

In this arrangement, the walls 15 of the body 12 are preferably made of a material which, relative to the absorption characteristics of the closure means material, is generally nonabsorbant of, and thus generally transparent to, the radiant energy used to melt the closure means 26. Thus, as radiant energy is applied to melt the closure means 26, the walls 15 are not themselves heated to any great extent. Rather, the walls 15 serve to pass the radiant energy directly to the closure means 26. The transfer of radiant heat to the closure means 26 thus remains fast and efficient.

Furthermore, as can be seen in Figs. 1 through 4, the axis of the ports 20 on one of the walls 15 are preferably laterally spaced from each of the axis of the ports 20 disposed in the opposite wall 15. Thus, as can be seen diagramatically in Fig. 3, radiant energy can be applied from an external source 18 across the interior 16 of the device 10 to melt a selected one of the closure means 26.

In order to assure that the maximum possible level of sterility is achieved, the device 10 preferably forms a component part of a fluid transfer assembly 28 shown in Fig. 1. In this assembly 28, the attachment means 22 includes connector means 30 which is attachable to the end portion of the fluid conduit 24.

As is shown in Figs. 2 and 3, the connector means 30 is operative for secure engagement within the attachment means 22 of the device 10. A positive connection between the device 10 and the conduit 24 is thus assured.

The connector means 30 also includes, like the ports 20 associated with the device 10, closure means 32 for normally sealing each connector means 30, and thus the fluid conduit 24 itself, from communication with the atmosphere.

The closure means 32 associated with each connector means 30 is also selectively removable to open the conduit 24 to fluid flow. Preferably, the closure means 32 is removable in the identical manner as the closure means 26 associated with the ports 20.

The connector means 30 may be variously constructed. However, in the illustrated embodiment (see, in particular, Figs. 2 through 4), each connector means 30 includes a tubular housing 36 which defines a hollow interior 38. The closure means 32 preferably takes the form of a meltable, radiant energy absorbing wall which normally seals or closes the interior 38 from communication with the atmosphere.

Each housing 36 further includes a tubular passage portion 40 (see Fig. 1) which communicates with the interior 38 and which serves to interconnect the housing 36 with its associated length of fluid conduit 24.

While the housing 36 may be variously attached to the end of the conduit 24, in the illustrated embodiment, a hermetic, friction fit with the tubular passage portion 40 is envisioned. As is shown in Fig. 1, an elastic band 42, such as one made from a latex material, preferably encircles the outer periphery of the junction to assure a fluid-tight, hermetic fit between the passage portion 40 and the respective conduit 24.

As is also best shown in Fig. 1, to normally prevent fluid flow communication with the interior 38 of the housing 36, an inline valve member 44 is provided. While the valve member 44 may be variously constructed, in the illustrated embodiment, it takes the form of a inline frangible valve member such as the valve member disclosed in Carter et al, U.S. Patent No. 4,294,247.

Alternately, the frangible valve member 44 can form an integral part of the connector housing 36, as is generally shown in Granzow et al, U.S. Patent No. 4,265,280.

To permit the transmission of radiant energy through the housing 36 onto the closure means 32, the housing 36, like the walls 15 of the device 10, is preferably made of material which does not absorb, and is thus transparent to, the particular type of radiant energy selected.

In the preferred embodiment, the closure means 26 and 32 are both made of a material fabricated from poly(4-methyl-1-pentene) which is sold under the trademark TPX by Mitsui Chemical Company. This material has a crystalline melting point of approximately 235°C and is further discussed in Boggs et al, U.S. Patent No. 4,325,417. The material of the closure means 26 and 32 includes a carbon filler so as to absorb virtually any type of radiant energy which lies in a continuous band encompassing infrared, visible, and ultraviolet radiation. The walls 15 of the device 10 and the housing 36 of the connector means 30 are each made of a clear TPX material which is generally transparent to the passage of radiant energy lying in this band.

As can best be seen in Figs. 2 through 4, in this arrangement, the attachment means 22 of the device 10 also includes a diametrically spaced pair of upstanding shoulders 46 peripherally surrounding each port 20. As shown in Fig. 2, the shoulders 46

are resiliently deformable axially outwardly of the axis of the associated port 20. A locking groove 48 (see Figs. 2 through 4) is formed circumferentially about the interior of each of the shoulders 46.

In this arrangement, the housing 36 of each of the connector means 30 includes a locking ridge 50. As can be seen in phantom lines in Fig. 2, as the connector means 30 is inserted between the shoulders 46, the ridge 50 resiliently deforms the shoulders 46 axially outwardly. As is shown in Figs. 3, the ridge 50 locks into a secure snap-fit engagement with the groove 48 at the time the closure means 26 and 32 are in facing contact.

In an alternate arrangement, the attachment means 22 could take the form of a twist lock, screw, or other snap-fit arrangement which securely interlocks the connector means 38 and the device 10 with the closure means 26 and 32 in facing contact.

As is shown in Figs. 3 and 4, when the facing closure means 26 and 32 are jointly exposed to the radiant energy source 18, which, in the illustrated embodiment, consists of incandescent quartz lamp having a tungsten filament operating at about 3150° K. As is shown diagramatically in Fig. 3, the lamp is focused on the radiant energy-absorbing closure means 26 and 32. In response to this exposure, the closure means 26 and 32 melt and fuse together, as can be seen in Fig. 4. In the process of melting, the closure means 26 and 32 form the hermetically sealed fluid path 34 which is at once sterile and closed to communication with the atmosphere.

In an alternate arrangement, one of the closure means 26 or 32 could be made of a meltable transparent material which would melt by conductive heat transfer as the other opaque closure means 26 or 32 melts in response to radiant heat.

It has been determined that utilization of a pair of radiant energy absorbing closure means, such as those associated with the assembly 28, assures a fluid connection having a probability of non-sterility which exceeds 10^{-6} (i.e., one in a million).

EXAMPLE

A methanol suspension of 1.5×10^8 Bacillus subtilis var niger (globiguii) spores per milliliter was prepared. This organism was chosen because of its high resistance to dry heat (see Angelotti, et al, "Influence of Spore Moisture Content on the Dry Heat Resistance of Bacillus subtilis var niger", Appl. Microbiol., v 16 (5): 735-745, 1968).

Eighty (80) uncoupled sterilized connector members (i.e., forty (40) pairs) having meltable walls made of TPX were inoculated with 0.01 milliliter of the B subtilis var niger (globiguii) suspension. This constituted exposure of the associated wall of each connector to approximately one million (i.e., 10^6) spores of the organisms.

Forty (40) of the inoculated uncoupled connectors were each attached to empty, sterile containers. The other forty (40) were each attached to containers containing a sterile microbiological

growth medium (soybean casien digest (SCD) broth). These inoculated pairs of connector members will hereafter be referred to as the Test Connectors.

Sixteen (16) additional uncoupled and sterilized connector members (i.e., eight (8) pairs) were inoculated only with methanol. Eight (8) of the connectors were each attached to empty, sterile containers, and eight (8) were each attached to sterile containers containing the SCD broth. These will hereafter be referred to as Negative Control Connectors.

The Test Connectors were coupled together, forming forty (40) connections between the empty containers and the SCD broth containers. The noninoculated Negative Control Connectors were also coupled together, forming eight (8) connections between the empty containers and the SCD broth containers. Each connection was exposed to the quartz lamp radiant energy source as heretofore described to fuse the walls together and open a fluid path. The medium was then passed through the connections.

Eight (8) additional and already fused connector members were inoculated as Positive Controls. Two of these connections were inoculated with a theoretical challenge of 10^6 B subtilis var niger (globigii) spores per connection; two were inoculated with a theoretical challenge of 10^4 spores per connection; two were inoculated with a

theoretical challenge of 10^2 spores per connection; and two were inoculated with a theoretical challenge of 10^1 spores per connection. Medium was the flushed through the fluid path of these Positive Control Connectors.

All units were incubated at approximately 32° to 37°C for up to seven days. After incubation, all turbid broths were subcultured to SCD agar and incubated for 18 to 24 hours at approximately 32° to 37°C. The subcultures were examined for the presence of orange colonies, which is characteristic of the indicator organism.

Upon examination of the forty (40) Test Connections, no turbid broths were observed.

All eight (8) Negative Controls also remained negative during incubation.

All eight (8) Positive Controls demonstrated growth of the indicator organism at all inoculum levels.

Attention is now directed to Fig. 5. There, a sterile fluid transfer system 54 is shown which is suited for use in the compounding of hyperalimentation solutions and the like. To assure sterility during compounding, the system 54 includes a multiple access fluid transfer assembly 28 as heretofore described.

The system 54 also includes one or more sources 56 of fluid. In hyperalimentation therapy, one of the sources 56 would contain a protein; one would contain a carbohydrate; one would contain a vitamin, etc.

Each fluid source 56 includes an integrally attached fluid conduit 58 which conducts fluid from the source 56. One connector means 30 is attached at the end of each fluid conduit 58.

The system 54 also includes one or more fluid receiving receptacles 60. The hyperalimentation solution will be compounded, or mixed, in this receptacle 60.

Each receptacle 60 includes an integrally attached fluid conduit 62 which serves to conduct fluid into the receptacle 60. One connector means 30 is attached to the end of the conduit 62.

In accordance with the invention, using the assembly 28, the protein, carbohydrate, and vitamin fluids contained in the sources 56 can be compounded, or mixed, in one or more of the fluid receiving receptacles 60. As already explained, this compounding can occur in a manner which does not breach the sterile integrity of the sources 56, the receptacles 60, or of any of the formed solutions.

More particularly, the connector means 30 associated with the fluid sources 56 of the fluid ingredients can be attached to the ports 20 on one of the walls 15 of the device 10. The connector means 30 associated with one or more of the fluid receiving receptacles 60 can be attached to a port 20 on the oppositely facing wall 15.

By applying radiant energy to jointly melt the facing closure means 26 and 32 (as shown in Figs. 3 and 4), and by breaking the associated frangible valve members 44, the fluid ingredients can be transferred by gravity from the attached sources 56 into the attached fluid receptacles 60.

If desired, inline roller clamps 64 or the like can be operatively connected with each conduit 58 and 62 to meter the transfer of fluids.

As shown in phantom lines in Fig. 5, the devices 10 may be manufactured and packaged in a unit 11 comprising a plurality of the devices 10. In this arrangement, the devices 10 may be joined together with a frangible connection 55 along adjacent walls 15. Each device 10 can be broken away from the unit 11 at the time of use.

An alternate embodiment of a fluid mixing system 55 which utilizes the fluid transfer assembly 28 is shown in Fig. 6. In this arrangement, the conduit 58 which is integrally attached with the fluid receiving receptacle 60 is itself integrally attached to one port 20 of the fluid transfer device 10. The transfer of fluids from the sources 56 into the receiving receptacle can progress as heretofore described, except that, in this embodiment, there is no need to form a connection between the fluid receiving receptacle 60 and the device 10.

In yet another alternate embodiment (not shown), the device 10 can be integrally attached (as in Fig. 6) to a length of tubing communicating with the peritoneal cavity of a patient on peritoneal dialysis. The connector means 30 would be carried at the end of a conduit which communicates with a dialysate container. To this arrangement, the multiple connections required during the course of peritoneal dialysis can be sequentially accommodated via the device 10 to introduce and drain the dialysate.

Various of the features of the invention are set forth in the following claims.

CLAIMS:

1. A multiple access fluid transfer device comprising

a body having wall means for defining a hollow interior,

entry means for defining at least two ports in said wall means communicating with said hollow interior,

means for selectively attaching the end portion of a conduit in communication with each of said ports, and

closure means extending across each of said ports for normally sealing said ports and being operative for removal to open a fluid path through said associated port only in conjunction with an active sterilization step which serves to sterilize the regions adjacent said fluid path.

2. A multiple access fluid transfer device according to claim 1

wherein said closure means is made of a material which melts in response to exposure to energy sufficient to sterilize said closure means.

3. A multiple access fluid transfer device according to claim 2

wherein said closure means is made of a material which melts in response to exposure to radiant heat energy.

4. A multiple access fluid transfer device according to claim 2 or 3

wherein said body wall means is made of a material which generally does not absorb the energy used to melt said closure means.

5. A multiple access fluid transfer device according to claim 3

wherein said body wall means is made of a material which is generally transparent to the radiant energy used to melt said closure means.

6. A multiple access fluid transfer device according to claim 3

wherein the radiant energy which is used to melt said closure means includes infrared radiation.

7. A multiple access fluid transfer device according to claim 3 or 6

wherein the radiant energy which is used to melt said closure means includes visible light.

8. A multiple access fluid transfer device according to claim 1 or 2 or 3

wherein said body wall means includes at least two diametrically spaced walls,

wherein said entry means includes at least one port in each of said diametrically spaced walls, and

wherein said removable closure means normally seals each of said ports.

9. A multiple access fluid transfer device according to claim 8

wherein said ports are each axially spaced along the respective one of said spaced walls with the axis of each of said ports defined in one of said walls being also axially spaced from the axis of each of said ports defined in the other one of said walls.

10. A multiple access fluid transfer device according to claim 8

wherein said spaced walls are each made of a material which generally does not absorb the energy used to melt said closure means.

11. A multiple access fluid transfer device according to claim 10

wherein the energy used to melt said closure means is radiant energy.

12. A multiple access fluid transfer device according to claim 11

wherein the radiant energy includes infrared radiation.

13. A multiple access fluid transfer device according to claim 11

wherein the radiant energy includes visible light.

14. A multiple access fluid transfer device according to claim 8

wherein said entry means defines at least two ports in one of said diametrically spaced walls.

15. A multiple access fluid transfer device according to claim 14

wherein said entry means defines a plurality of ports in said one wall.

16. A multiple access fluid transfer device according to claim 15

wherein said entry means defines at least two ports in the other one of said walls.

17. A fluid transfer assembly comprising a multiple access fluid transfer device comprising

a body having wall means for defining a hollow interior,

entry means for defining at least two ports in said wall means communicating with said hollow interior, and

closure means extending across each of said ports for normally sealing said ports from communication with the atmosphere,

connector means attachable to the end of a fluid conduit and including closure means for normally sealing said connector means from communication with the atmosphere,

attachment means for coupling one of said connector means to one of said ports with said closure means of said one connector means in facing contact with said closure means of said one port, and

said closure means of said one connector means and said one port each being further operative for melting only in response to exposure to sterilization temperatures and, when disposed in said facing contact and exposed to said sterilization temperatures, for fusing together and forming an opening to establish a fluid path which is sterile and closed to communication with the atmosphere.

18. A fluid transfer assembly according to claim 17

wherein said fluid path formed presents a probability of non-sterility which is at least 10^{-6}.

19. A fluid transfer assembly according to claim 17

wherein said closure means is made of a radiant energy absorbing material and melts in response to exposure to a source of radiant energy sufficient to effectively sterilize said closure means.

20. A fluid transfer assembly according to claim 19

wherein said body wall means is made of a material which is generally transparent to the radiant energy used to melt said closure means.

21. A fluid transfer assembly according to claim 20

wherein said radiant energy includes infrared radiation.

22. A fluid transfer assembly according to claim 17

wherein said body wall means includes at least two diametrically spaced walls,

wherein said entry means includes at least one port in each of said diametrically spaced walls, and

wherein said meltable closure means normally seals each of said ports.

23. A fluid transfer assembly according to claim 22

wherein said ports are each axially spaced along the respective one of said spaced walls with the axis of each of said ports defined in one of said walls being also axially spaced from the axis of each of said ports defined in the other one of said walls.

24. A fluid transfer assembly according to claim 22

wherein said entry means defines at least two ports in one of said diametrically spaced walls.

25. A fluid transfer assembly according to claim 24

wherein said entry means defines a plurality of ports in said one wall.

26. A fluid transfer assembly according to claim 25

wherein said entry means defines at least two ports in the other one of said walls.

27. A sterile fluid transfer system comprising

at least two sources of fluid,

at least one fluid receiving receptacle, and

a fluid transfer assembly as defined in any one of claims 17 through 26 and wherein one of said connector means communicates with each of said fluid sources and each of said fluid receiving receptacle,

whereby fluid from said fluid sources may be transferred in a sterile fashion into each of said fluid receiving receptacles using said fluid transfer assembly.

FIG. 1

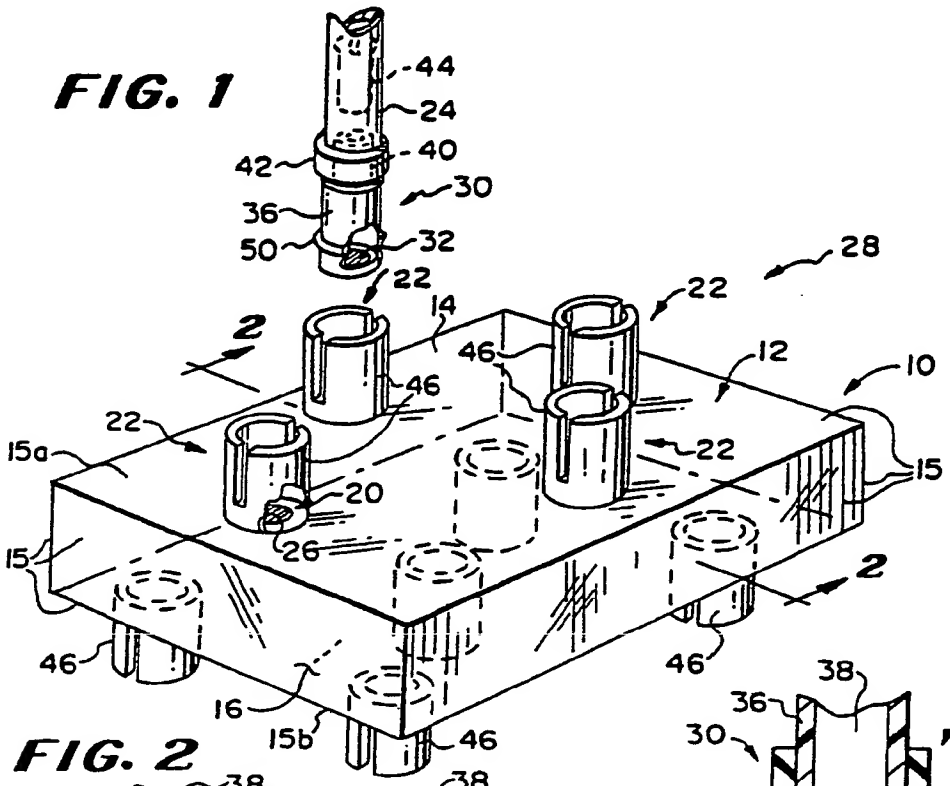


FIG. 2

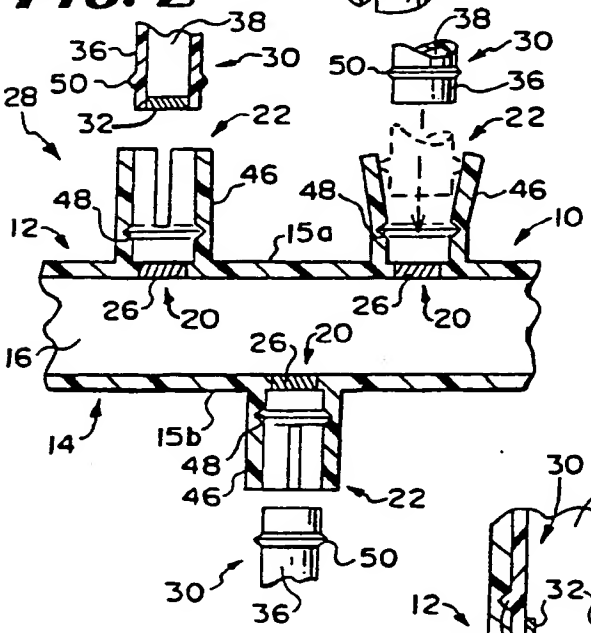


FIG. 3

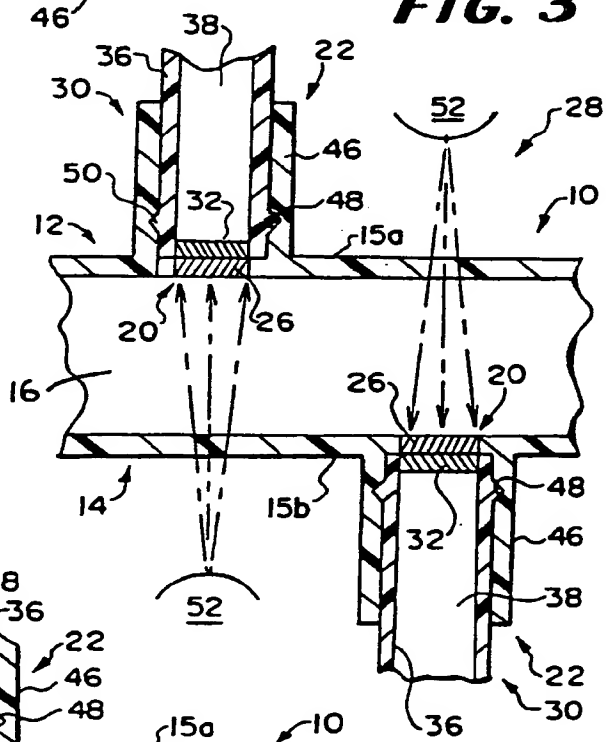
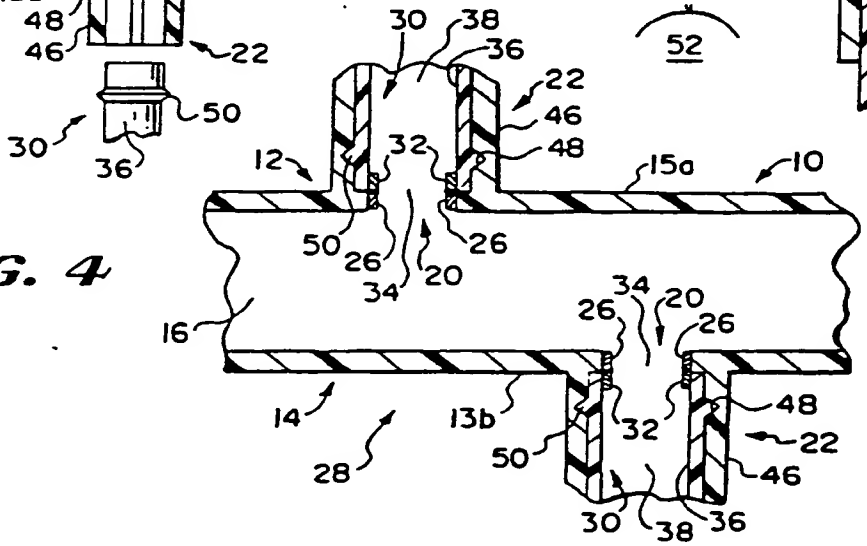


FIG. 4



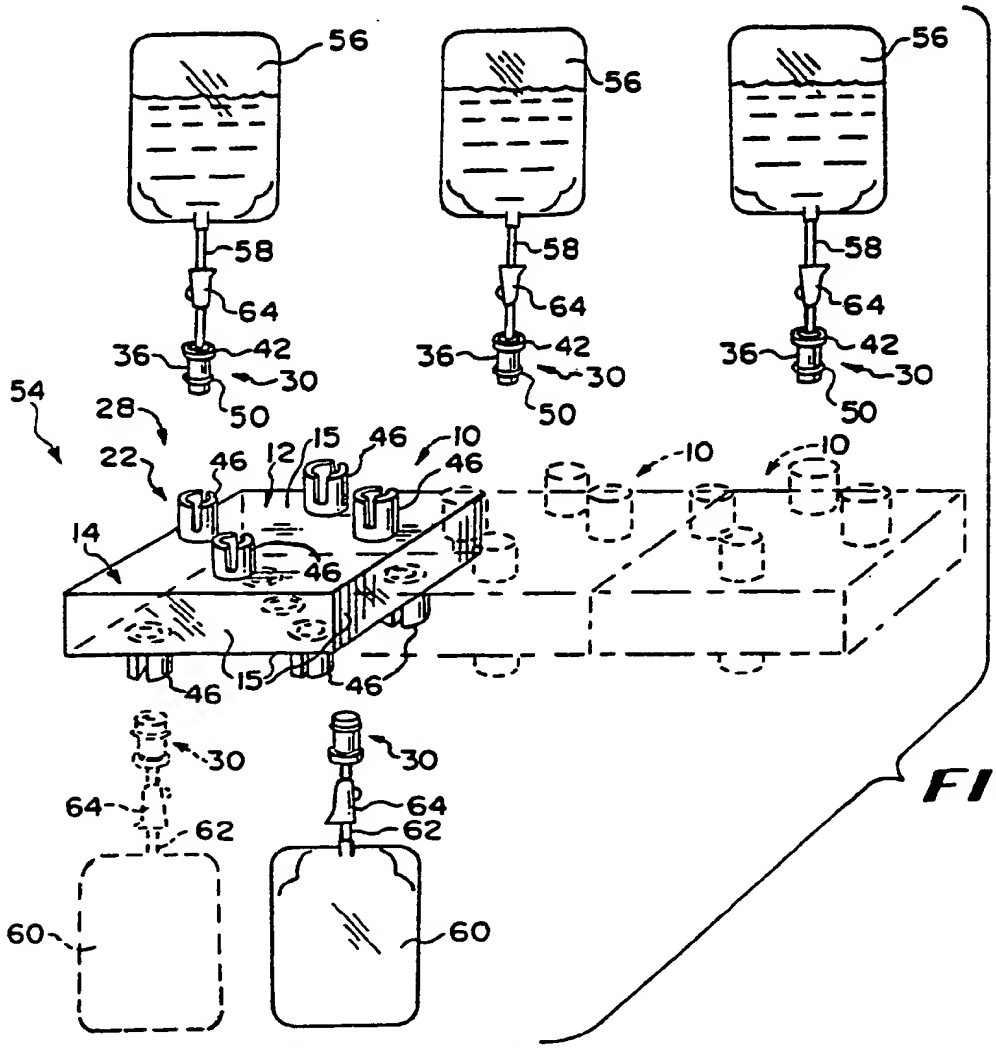


FIG. 5

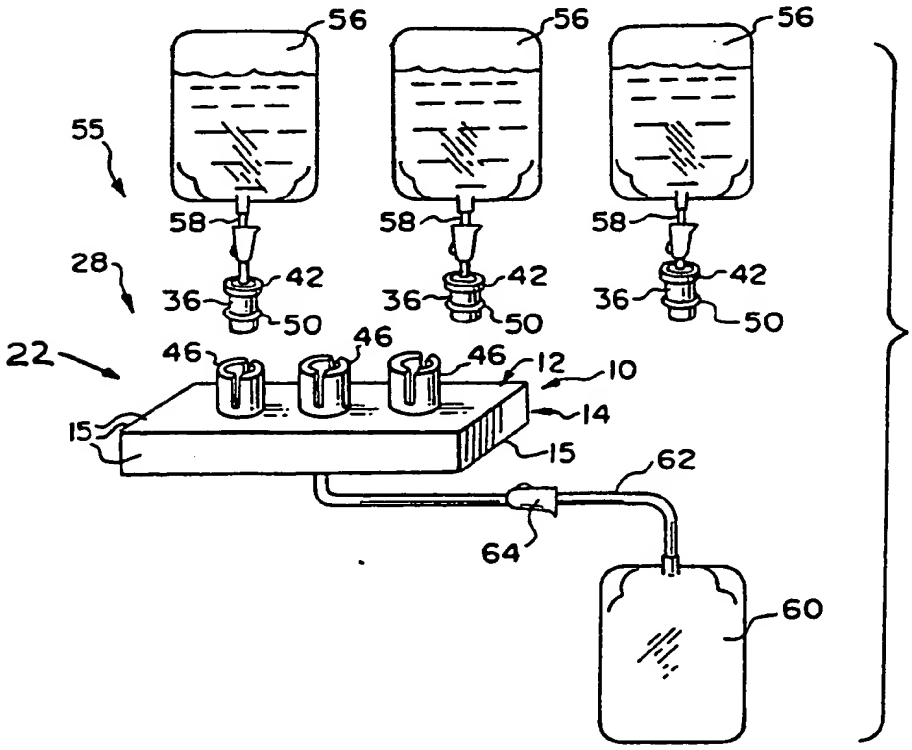


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 83/00958

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC 219/221LK,221LL;
INT. CL. 3 B65 B 3/04 141/1,98,114,311R,382-388,392;
U.S. CL. 222/541;250/338;285/3,4,67,325;156/251,252,253,261,250

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	285/314,67,325 604/905,414,244, 156/250,251,252,253,261,272, 289,306,141/1,98,114,311R,382-388,392

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

156/272,289,306;604/905,414,244

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y	US, A, 4,265,280,published May 5,1981	1-27
Y	US, A, 4,298,001,published November 3,1981	1-27
A	US, A, 4,325,417,published April 20,1982	1-27

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [3]
15 September 1983	27 SEP 1983
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/U.S.	Houston Bell HOUSTON S. BELL, JR.

Form PCT/ISA/210 (second sheet) (October 1981)